

Congress of the United States

Washington, DC 20515

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. McClellan:

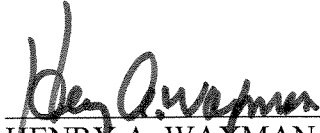
We are enclosing a comment in response to your March 13, 2003, request for comments on qualified health claims for foods (Public Docket No. 03N-0069). As described in the comment, we believe that Food and Drug Administration (FDA) has exceeded its authority in permitting health claims for foods that do not meet standard for such claims in the Nutrition Labeling and Education Act.

We also ask that you provide answers to the following questions:

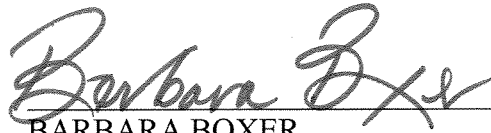
1. Is it the position of the Food and Drug Administration that an agency's enforcement discretion authorizes the agency to refuse to enforce clear statutory standards for whole classes of products or regulated entities for indefinite periods of time and without any intention that the statutory standards will ultimately be met?
2. Is it the position of the Food and Drug Administration that, under the theory enunciated in the December 20 guidance document, the FDA could issue a similar document that announces that the agency will (a) no longer enforce the requirement that drugs be shown to be effective before they are promoted for specific uses, or (b) refuse to enforce the requirement if drug manufacturers meet some lower nonstatutory standard crafted by the agency?
3. Are there other statutory approval or review standards in the Federal Food, Drug, and Cosmetic Act that you believe the FDA could refuse to enforce under circumstances similar to those listed in the December 20 guidance?
4. If this action was motivated in part by concern that the FDA has been too slow in granting legitimate health claims for foods, please explain why the answer to this problem is to ignore a statutory standard rather than to improve the quality and speed of the approval process (as has been done for drugs).

Thank you for your co-operation with these requests. Please provide your responses to these questions by June 13, 2003. If you have any questions, you may call Ann Witt on Mr. Waxman's staff (202-225-3976).

Signed,



HENRY A. WAXMAN
United States House of Representatives



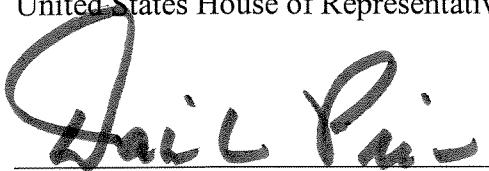
BARBARA BOXER
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